

FOOD AND DRUG ADMINISTRATION  
Center for Drug Evaluation and Research  
ANTIVIRAL DRUGS ADVISORY COMMITTEE (AVAC) MEETING

**AGENDA**  
December 12, 2001

Holiday Inn –Bethesda, Maryland

Topic: An update on the approval of BLA 103949/5002, PEG-Intron™ (peginterferon alfa-2b) Powder for Injection, indicated for use alone or in combination with Rebetol (ribavirin, USP) for the treatment of chronic hepatitis C in patients with compensated liver disease who have not been previously treated with interferon alpha and are at least 18 years of age.

8:15 a.m.	Call to Order	Roy M. Gulick, M.D., M.P.H. Chair, AVAC
	Introduction of Committee	
	Conflict of Interest Statement	Tara P. Turner, Pharm.D. Executive Secretary, AVAC
8:30 a.m.	<b>Sponsor Presentation</b>	Schering Corporation
	Introduction	Dr. P. Giles Director, Regulatory Affairs
	Advances in the Treatment of Chronic Hepatitis C	Dr. J. Albrecht Vice President, Clinical Research
	Risk:Benefit Decisions in Treating Patients with Chronic Hepatitis C	Dr. J. McHutchinson Medical Director, Liver Transplantation Scripps Clinic
9:00 a.m.	<b>FDA Presentation</b>	Louis Marzella, M.D., Ph.D. Medical Officer Division of Clinical Trial Design and Analysis Center for Biologics Evaluation and Research FDA
9:30 a.m.	Questions to Presenters	
10:00 a.m.	Open Public Hearing	
		Brian Klein – Hepatitis C Advocacy and Action Coalition (HAAC) Jules Levin – National AIDS Treatment Advocacy Project (NATAP) Kathleen Schwarz, M.D. - Chief, Pediatric Gastroenterology and Nutrition Johns Hopkins Medical Center
11:00 a.m.	Committee Discussion	
12:15 p.m.	Adjourn	

